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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,576	10/17/2005	Mitsuharu Hirai	TOYA114.008APC	4658
20995 7590 08/23/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER STAPLES, MARK	
			ART UNIT 1637	PAPER NUMBER
			NOTIFICATION DATE 08/23/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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# Office Action Summary

Application No.

10/553,576

Applicant(s)

HIRAI, MITSU HARU

Examiner

Mark Staples

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____   | 6) <input type="checkbox"/> Other: ____                           |

## DETAILED ACTION

### *Group Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4 and 7 in part, drawn to methods for detecting and quantifying a DNA having mitochondrial 3243 mutation using primers starting from nucleotide number 243 in SEQ ID NO: 1; which can be primers having the nucleotide sequence of SEQ ID NOs: 3 and 5 and a probe sequence starting from 212 or 215 of SEQ ID NO: 1.

Group II, claim(s) 1-4 and 7 in part, drawn to methods for detecting and quantifying a DNA having 3243 mutation using primers starting from nucleotide number 243 in SEQ ID NO: 1; which can be primers having the nucleotide sequence of SEQ ID NOs: 3 and 5 and a probe sequence starting from 222 of SEQ ID NO: 2.

Group III, claim(s) 5-7 in part, drawn to methods for detecting a DNA having mitochondrial 3243 mutation using primers starting from nucleotide number 243 in SEQ ID NO: 1; which can be primers having the nucleotide sequence of SEQ ID NOs: 3 and 4 and a probe sequence starting from 212 or 215 of SEQ ID NO: 1.

Group IV, claim(s) 5-7 in part, drawn to methods for detecting a DNA having mitochondrial 3243 mutation using primers starting from nucleotide number 243 in SEQ ID NO: 1; which can be primers having the nucleotide sequence of SEQ ID NOs: 3 and 4 and a probe sequence starting from 222 of SEQ ID NO: 2.

Group V, claim(s) 8-13 and 15-16 in part, drawn to kits of primers starting from nucleotide number 243 in SEQ ID NO: 1 which can comprise primers having the nucleotide sequence of SEQ ID NOs: **3 and 5** and a probe sequence starting from 212 or 215 of SEQ ID NO: 1.

Group VI, claim(s) 8-13 and 15-16 in part, and claim 17 in part, and claims 22-24 in part, drawn to kits of primers starting from nucleotide number 243 in SEQ ID NO: 1 which can comprise primers having the nucleotide sequence of SEQ ID NOs: **3 and 5** and a probe

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sequence starting from 222 of SEQ ID NO: 2 where the probe can have the nucleotide sequence SEQ ID NO: 21.

Group VII, claim(s) 8-13 and 15-16 in part, and claim 17 in part, and claims 22-24 in part, drawn to kits of primers starting from nucleotide number 243 in SEQ ID NO: 1 which can comprise primers having the nucleotide sequence of SEQ ID NOs: **3 and 5** and a probe sequence starting from 222 of SEQ ID NO: 2 where the probe can have the nucleotide sequence SEQ ID NO: 22.

Group VIII, claim(s) 8-11, 14, and 15-16 in part, drawn to kits of primers starting from nucleotide number 243 in SEQ ID NO: 1 which can comprise primers having the nucleotide sequence of SEQ ID NOs: **3 and 4** and a probe sequence starting from 212 or 215 of SEQ ID NO: 1.

Group IX, claim(s) 8-11, 14, and 15-16 in part, and claim 17 in part, and claims 22-24 in part, drawn to kits of primers starting from nucleotide number 243 in SEQ ID NO: 1 which can comprise primers having the nucleotide sequence of SEQ ID NOs: **3 and 4** and a probe sequence starting from 222 of SEQ ID NO: 2 where the probe can have the nucleotide sequence SEQ ID NO: 21.

Group X, claim(s) 8-11, 14, and 15-16 in part, and claim 17 in part, and claims 22-24 in part, drawn to kits of primers starting from nucleotide number 243 in SEQ ID NO: 1 which can comprise primers having the nucleotide sequence of SEQ ID NOs: **3 and 4** and a probe sequence starting from 222 of SEQ ID NO: 2 where the probe can have the nucleotide sequence SEQ ID NO: 22.

Group XI, claim(s) 18-21 in part, drawn to methods for detecting a mutation using a probe sequence starting from 222 of SEQ ID NO: 2 wherein the probe can have the nucleotide sequence SEQ ID NO: 21.

Group XII, claim(s) 18-21 in part, drawn to methods for detecting a mutation using a probe sequence starting from 222 of SEQ ID NO: 2 wherein the probe can have the nucleotide sequence SEQ ID NO: 22.

2. This International Searching Authority considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2, 13.3) for the reasons indicated below:

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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The special technical feature linking Groups I-XII appears to be that they all relate to a DNA having mitochondrial 3243 mutation. However, Majamaa et al. (1998) teach a DNA having mitochondrial 3243 mutation (see Title).

Therefore, the technical feature linking the inventions of Groups I-XII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-XII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

### ***Species Election/Restrictions***

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required to further elect species as follows.

For Groups I-X, Applicant is required to elect and specify **two** primer sequences and **one** probe sequence. The nucleotides in each sequence must be listed in accordance with Sequence Rules and be identified by a SEQ ID NO.

Applicant may elect a sequence already disclosed in a group. *For example, one possible election for Group VI would be the disclosed sequences of primer sequences SEQ ID NOs: 3 and 5 and the probe sequence SEQ ID NO: 21.*

For Groups XI and XII, Applicant is required to elect and specify **one** probe sequence. The nucleotides in each sequence must be listed in accordance with Sequence Rules and be identified by a SEQ ID NO.

Applicant may elect a sequence already disclosed in a group. *For example, one possible election for Group XI would be the disclosed sequence of probe sequence SEQ ID NO: 21.*

### ***Notice of Possible Rejoinder***

4. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are

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subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Close***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-

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9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 7:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples  
Examiner  
Art Unit 1637  
August 16, 2007

TERESA E. STRZELECKA, PH.D.  
PRIMARY EXAMINER

*Teresa Strzelecka*

*8/17/07*